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TRAN	NSMITTA	L OF INFORMA (Under 37 CFF	TION DISCLOSURE STA R 1.97(b) or 1.97(c)	ATEMENT	41	cket No. 6096					
In Re Ap	pplication Of	: Richard James I	Lewis et al. JUL 0 3 2006			•					
Applic	ation No.	Filing Date	ExaminerMARK	Customer No.	Group Art Unit	Confirmation No.					
10/5	37,088	June 2, 2005	Unassigned	23389	Unassigned	9222					
Title: NOVEL X-CONOTOXIN PEPTIDES (-II)											
÷	Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450										
			37 CFR 1.97(b)								
1. 🛚	of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114. 37 CFR 1.97(c)										
	otherwise	closes prosecution in	 1.113, a Notice of Allowance n the application, and is accom 	panied by one (of:						
	☐ the	statement specified	in 37 CFR 1.97(e);								
			OR								
	☐ the	fee set forth in 37 Cl	FR 1.17(p).								

TRÁNSMITTA		TION DISCLOSURE	STATEMENT	181	cket No. 6096
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10/537,088	June 2, 2005	Unassigned	23389	Unassigned	9222
Title: NOVEL X-0	CONOTOXIN PEPT	IDES (-II)			
	(Only on	Payment of I nplete if Applicant elects to pay	ee the fee set forth in 3	7 CFR 1.17(p))	
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Applicants:

Richard James Lewis et al.

Examiner:

Unassigned

Serial No:

10/537,088

Art Unit:

Unassigned

Filed:

June 2, 2005

Docket:

16096

For:

NOVEL χ -CONOTOXIN PEPTIDES (-II) **Dated:**

June 28, 2006

Confirmation No: 9222

Mail Stop Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. International Publication No. WO 98/22126, published May 28, 1998;

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on June 28, 2006.

Dated: June 28, 2006

- 2. International Publication No. WO 91/07980, published June 13, 1991;
- 3. International Publication No. WO 96/14079, published May 17, 1996;
- 4. International Publication No. WO 96/40064, published December 19, 1996;
- 5. International Publication No. WO 98/05309, published February 12, 1998;
- 6. International Publication No. WO 98/02148, published January 22, 1998;
- 7. International Publication No. WO 98/51668, published November 19, 1998;
- 8. International Publication No. WO 97/30997, published August 28, 1997;
- 9. International Publication No. WO 97/01351, published January 16, 1997;
- 10. United States Patent No. 6,767,896 B1, dated July 27, 2004, issued to McIntosh et al.;
- 11. United States Patent No. 6,794,361 B1, dated September 21, 2004, issued to Lewis et al.;
- 12. United States Patent No. 5,587,454, dated December 24, 1996, issued to Justice et al.;
- 13. United States Patent Application Publication No. 2005/0054827 A1, dated March 10, 2005 to Lewis et al.;
- 14. Bowersox, S.S. et al., "Selective N-Type Neuronal Voltage-Sensitive Calcium Channel Blocker, SNX-111, Produces Spinal Antinociception in rat Models of Acute, Persistent and Neuropathic Pain", *J. Pharmacol Exp. Ther.*, 279 (3): 1243-1249 (1996);
- 15. Krames, Elliot S. et al., "Intrathecal D-Ala²⁻D-Leu⁵-enkephalin (DADL) Restores Analgesia in a Patient Analgetically Tolerant to Intrathecal Morphine Sulfate", *Pain*, 24: 205-209 (1986);
- Takagi, H. et al., "Analgesic Effect of L-threo-3-4-dihydroxyphenylserine (L-DOPS) in Patients with Chronic Pain", European Neuropsychopharmacology, 6: 43-47 (1996);
- 17. Eisenach, C. et al., "Cerebrospinal Fluid Norepinephrine and Acetylcholine Concentrations During Acute Pain", *Anesth Analg*, 82: 621-626 (1996);
- 18. Dubner, R. et al., "The Neurobiology of Pain and Its Modulation", *The Clinical Journal of Pain, 5(Suppl 2)*: S1-S6 (1989);

19. Dyck, P.J et al., "New Understanding and Treatment of Diabetic Neuropathy", The New England Journal of Medicine, 326(19):1287-1288 (1992);

1

- 20. Atkinson, J. H. et al., "A Placebo-controlled Randomized Clinical Trial of Nortriptyline for Chronic Low Back Pain", *Pain*, 76: 287-296 (1998);
- 21. Mico, J. A., et al., "Analgesic, Sedative and Antidepressent Effects of Noradrenergic Antidepressants Related to Beta-Adrenoceptors", *European Neuropsychopharmacology*, S162, P.1.086, Abstract (1997);
- 22. Springer, J. P. et al., "Facilitatory and Inhibitory Effects of Selective Norephinephrine Reuptake Inhibitors on Hypogastric Nerve-Evoked Urethral Contractions in the Cat: A Prominent Role of Urethral β-Adrenergic Receptors", The Journal of Urology, 152: 515-519 (1984);
- 23. Dinan, T. G. et al., "Assessment of Central Noradrenergic Functioning in Irritable Bowel Syndrome Using a Neuroendocrine Challenge Test", *Journal of Psychosomatic Research*, 34(5): 575-580 (1990);
- 24. Leung, D. et al., "Protease Inhibitors: Current Status and Future Prospects", J. Med Chem, 43(3): 305-341 (2000);
- 25. O'Neill, M. J. et al., "Effects of Ca²⁺ and Na⁺ channel inhibitors in vitro and in global cerebal ischaemia in vivo", *European Journal of Pharmacology*, 332: 121-131 (1997);
- 26. Eisenach, J. C. et al., "Intrathecal, but Not Intravenous, Clonidine Reduces Experimental Thermal or Capsaicin-Induced Pain and Hyperalgesia in Normal Volunteers", *Anesth Analg, 87*: 591-596 (1998);
- 27. Marban, E. et al., "Structure and Function of Voltage-Gated Sodium Channels", *Journal of Physiology*, 508.3: 647-657 (1998);
- 28. Yanagawa, Y. et al., "A Novel Sodium Channel Inhibitor from *Conus geographus*: Purification, Structure, and Pharmacological Properties", *Biochemistry*, 27: 6256-6262 (1988);
- 29. Ryan, R., et al., "Evaluation of an Enkephalin Analog in Men with Castor Oil-Induced Diarrhea", *Clinical Pharmacol Ther*, 39(1): 40-42 (1986);
- 30. Penttila, O, et al., "Studies of Rectal Mucosal Catecholamines in Ulcerative Colitis", *Annals of Clinical Research*, 7: 32-36 (1975).

Applicants are submitting copies of Reference Numbers 1-9 and 14-30. In accordance with the waiver of 37 C.F.R. § 1.98 (a)(2)(i) in effect as of June 30, 2003, Applicants are not required to submit copies of the above-cited U.S. Patent Reference Numbers 10-13.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. §1.97(b), no statement or fee is required.

Respectfully submitted,

Xiaochun Zhu

Registration No. 56,311

Scully, Scott, Murphy & Presser, P.C. 400 Garden City Plaza – Suite 300 Garden City, New York 11530 (516) 742-4343

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	6,767,896 B1	7/27/2004	McIntosh	et al.				
	6,794,361 B1	9/21/2004	Lewis et a	ıl.				
	5,587,454	12/24/1996	Justice et	al.				
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	OTHER DOCUME	<u> </u>		, Title, Date, Pertinent F		<u> </u>		
	Bowersox, S.S. et al., "S Antinociception in rat N (1996)	elective N-Type I Iodels of Acute, I	Neuronal V Persistent a	Voltage-Sensitive Calcium (and Neuropathic Pain'', J. I	Channel Blo Pharmacol	ocker, SNX-111, Exp. Ther., 279	Produces (3): 1243-	Spinal 1249
	Krames, Elliot S. et al., Tolerant to Intrathecal	"Intrathecal D-A Morphine Sulfate	la2-D-Leu e'', Pain, 2	5-enkephalin (DADL) Rest 4: 205-209 (1986)	ores Analg	esia in a Patient	Analgetica	illy
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		Atkinson, J. H. et al., "A 76: 287-296 (1998)	Placebo-control	led Rando	mized Clinical Trial of Nor	triptyline f	or Chronic Low	Back Pain	", Pain,
		Mico, J. A., et al., "Anal Beta-Adrenoceptors", E	gesic, Sedative as uropean Neurop	nd Antide _l sychophar	pressent Effects of Noradre macology, S162, P.1.086, A	nergic Anti Abstract (19	depressants Rela 197)	ated to	
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	Leung, D. et al.	., "Protease Innibitors.	ing Author, Title, Date, F tral Noradrenergic Function tatic Research, 34(5): 575-56 Current Status and Future and Na+ channel inhibitors in 31 (1997)	in vitro and in glo	bal cerebal isch	naemia in vivo", Euro	
	O'Neill, M. J. o Journal of Pha Eisenach, J. C	et al., "Effects of Ca2+ a irmacology, 332: 121-13 . et al., "Intrathecal, bu eralgesia in Normal Vol	unteers", Anesth Analg, 87:	391-390 (1996)	mental Therma	d or Capsaicin-Induce	
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	(1998)	A Novel Sodium Chan	nel Inhibitor from Conus geog	graphus: Pu	urification, Stru	cture, and
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